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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,512	06/05/2001	David H. Sachs	59056,___	6693

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/874,512

Applicant(s)

SACHS, DAVID H.

Examiner

Anne Marie S. Wehbe

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 21 April 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 19-36.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ATTACHEMENT TO ADVISORY ACTION

5. cont. The rejection of claims 19-20, 23 and 24-34 under 35 U.S.C. 102(b) over Chavin et al. is maintained for reasons of record. The “instructions” in the kit are not structurally related to the anti-CD2 antibody or immunosuppressive agent and are not required for their functionality. Regarding *In re Gulack*, the “printed matter” in Gulack is not a set of “instructions” but rather numbers printed on the band element of the claimed composition. It is further noted that Gulack concerns an obviousness rejection and not an anticipation rejection. In Gulack, the court found that the numbers printed on the band were functionally related to the band substrate because the sequence of numbers in the claims was derived from a specific algorithm and locations of these numbers on the band were critical for the functionality of the device. Further, the art applied as 103 in Gulack did not teach or suggest the same set of numbers or their order on the band. The instant case is substantially different from Gulack. In the instant case, Chavin teaches the exact structural elements of the “kit”, namely an anti-CD2 antibody and an immunosuppressive agent and their use to increase graft survival and induce graft tolerance *in vivo*. Thus, unlike the case of Gulack, the exact elements of the claims are present in Chavin. Further, the “instructions” are not related structurally or functionally to the compositions. Note that the court in Gulack states that , “ Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability” *In re Gulack*, page 404. The instructions in the instant claims simply recite how to use the antibody to induce tolerance. However, Chavin clearly teaches using the anti-CD2 antibody and immunosuppressive agent to induce tolerance and the written instructions are not required for this functionality. Thus, the instructions recited in the claims do not meet the standard for functional relationship established in *In re Gulack*.

The rejection of claims 21-22, and 35-36 under 35 U.S.C. 103(a) as being unpatentable over Bazin et al., in view of Chavin et al. is maintained. The arguments directed to Chavin et al. have been addressed above. Regarding motivation to combine, the applicant’s arguments are based on the instructions as to how to administer the kit elements. As discussed

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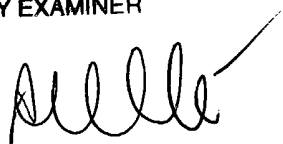
above, these instructions do not have patentable weight as they are not structurally or functionally related to the anti-CD2 antibody or immunosuppressive agent.

The rejection of claims 19-36 for indefiniteness under 35 U.S.C. 112, second paragraph, is maintained. The applicant argues that the specification provides ranges for appropriate dosages and thus the meaning of "high dose" can be determined. However, this is not agreed. The applicant has stated that Chavin et al. does not teach a "high dose" of immunosuppressive, and yet on page 737, Table 1, Chavin teaches administering cyclosporin at a dose of 15 mg/kg/day, the same dose taught in the specification, and Chavin et al. appears to consider this a "low dose". Therefore, since the meaning of "high dose" is clearly relative, the claims are indefinite.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a long horizontal stroke extending to the right.